UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

In re: ZYPREXA PRODUCTS LIABILITY LITIGATION

WILLIAM ASBURY,

Plaintiff,

- against –

ELI LILLY & COMPANY,

Defendant.

MEMORANDUM, ORDER & JUDGMENT

04-MD-1596

06-CV-1593

JACK B.WEINSTEIN, Senior United States District Judge:

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I. Introduction

Defendant Eli Lilly & Company ("Lilly") moves for summary judgment against William Asbury. Plaintiff commenced this action against Lilly in the United States District Court for the District of Kansas on January 31, 2006. The case was transferred to the Eastern District of New York pursuant to an order of the Judicial Panel on Multidistrict Litigation.

The action is essentially a negligence claim, based on a failure to warn. It seeks money damages for injuries, alleging that: (1) Zyprexa, a drug produced by Lilly, caused plaintiff's diabetes; (2) Lilly failed to warn of the dangers of Zyprexa; and (3) Zyprexa would not have been prescribed, and diabetes would not have been suffered, if proper warnings had been given. Lilly pleaded the statute of limitations as an affirmative defense. Ans. ¶ 69 (Ex. 1 to Jan. 4, 2010 Decl. of John F. Brenner ("Brenner Decl.")).

For the reasons indicated below, plaintiff's claim is barred by the applicable Kansas statute of limitations. Defendant's motion for summary judgment is granted.

II. Facts

The present case is part of a massive and highly complex multidistrict litigation that has included claims by individual Zyprexa users, state attorneys general, third-party payors, and other entities alleging physical or financial injury. Some 30,000 cases have been brought against Lilly by individual plaintiffs suffering from serious psychiatric problems who were treated with Zyprexa. Like the present plaintiff, they principally allege that Zyprexa caused deleterious side effects of excessive weight gain, hyperglycemia, and diabetes; that Lilly misled them and their physicians about the likelihood of these side effects; and that, had they or their attending physicians been aware of the risks, they would not have taken Zyprexa. The court has previously

detailed the procedural history and factual background of this multidistrict litigation. *See, e.g., Mississippi v. Eli Lilly & Co. (In re Zyprexa Prods. Liab. Litig.)*, --- F. Supp. 2d ---, Nos. 04-MD-1596, 07-CV-645, 2009 WL 4260857 (E.D.N.Y. Dec. 1, 2009); *Blume v. Eli Lilly & Co. (In re Zyprexa Prods. Liab. Litig.)*, Nos. 04-MD-1596, 06-CV-2782, 2009 WL 3596982 (E.D.N.Y. Oct. 20, 2009).

A. Contents and Use of Zyprexa

Zyprexa's active ingredient is olanzapine, one of a class of medications known as "atypical" or "second generation" antipsychotics. It was approved for use in treating schizophrenia and acute manic episodes associated with bipolar disorder by the United States Food and Drug Administration ("FDA") in 1996. In 2004, the FDA also approved Zyprexa for the treatment of bipolar disorder generally.

B. Labeling and Warnings to Patients and Medical Professionals

1. FDA Labeling and "Dear Doctor Letter"

The original 1996 Zyprexa package insert accompanying the drug disclosed information about possible side effects of administration of olanzapine based on clinical trials. The insert provided, in part, the following information:

> Adverse Events Occurring at an Incidence of 1% or More Among Olanzapine-Treated Patients in Short-Term, Placebo-Controlled Trials - - Table 1 enumerates the incidence, rounded to the nearest percent, of treatment-emergent adverse events that occurred during acute therapy (up to 6 weeks) of schizophrenia in 1% or more of patients treated with olanzapine (doses $\geq$ 2.5 mg/day) where the incidence in patients treated with olanzapine was greater than the incidence in placebo-treated patients.
>
> The prescriber should be aware that the figures in the tables and tabulations cannot be used to predict the incidence of side effects in the course of usual medical practice where patient

> characteristics and other factors differ from those that prevailed in the clinical trials. Similarly, the cited frequencies cannot be compared with figures obtained from other clinical investigations involving different treatments, uses, and investigators. The cited figures, however, do provide the prescribing physician with some basis for estimating the relative contribution of drug and nondrug factors to the side effect incidence in the population studies.

Zyprexa Package Insert 11 (Oct. 1, 1996) (original emphasis).

Two tables in the insert provided the results of placebo-controlled clinical studies of olanzapine-treated patients. The data indicates that, over a six-week administration of Zyprexa, six percent of olanzapine-treated patients reported weight gain, while only one percent of the placebo-treated patients reported weight gain. *Id.* at 12-16.

For several years, this information on the insert remained substantially the same insofar as it provided physicians information on reported weight-gain-related adverse events. During this period, the results of longer-term studies and clinical experience with Zyprexa and competing drugs supporting weight gain, hyperglycemia, and diabetes became widely known. *See* Part II.B.4, *infra.*

In May 2000, the FDA undertook an analysis of the incidence of diabetes and hyperglycemia in patients using atypical antipsychotics. The director of the FDA's Division of Neuropharmalogical Drug Products requested additional safety information about Zyprexa from Lilly. In its letter, the FDA cited post-marketing reports of diabetes-related adverse events associated with Zyprexa use. In response, Lilly provided the FDA with clinical studies, data analysis, and case report reviews. *See In re Zyprexa Prods. Liab. Litig.*, 253 F.R.D. 69, 119 (E.D.N.Y. 2008). There is disagreement about whether the information given by Lilly to the FDA was complete and accurate.

On September 11, 2003, the FDA announced it would require a warning about risks of hyperglycemia and diabetes mellitus and treating precautions to appear in the package insert of all atypical antipsychotics, including Zyprexa. Designed for prescribing doctors, the label noted that epidemiological studies and other information indicated that the relationship between the drug and hyperglycemia and diabetes was not yet fully understood. It reads as follows:

> **WARNINGS**
> **Hyperglycemia and Diabetes Mellitus**
> Hyperglycemia, in some cases extreme and associated with ketoacidosis or hypersomolar coma or death has been reported in patients treated with atypical antipsychotics including Zyprexa. Assessment of the relationship between atypical antipsychotic use and glucose abnormalities is complicated by the possibility of an increased background risk of diabetes mellitus in patients with schizophrenia and the increasing incidence of diabetes mellitus in the general population. Given these confounders, the relationship between atypical antipsychotic use and hyperglycemia-related adverse events is not completely understood. However, epidemiological studies suggest an increased risk of treatment-emergent hyperglycemia-related adverse events in patients treated with the atypical antipsychotics studied. Precise risk estimates for hyperglycemia-related adverse events in patients treated with atypical antipsychotics are not available. . . .
>
> Patients with an established diagnosis of diabetes mellitus who are started on atypical antipsychotics should be monitored regularly for worsening of glucose control. Patients with risk factors for diabetes mellitus (e.g., obesity, family history of diabetes) who are starting treatment with atypical antipsychotics should undergo fasting blood glucose testing at the beginning of treatment and periodically during treatment. Any patient treated with atypical antipsychotics should be monitored for symptoms of hyperglycemia including polydipsia, polyuria, polyphagia, and weakness. Patients who develop symptoms of hyperglycemia during treatment with atypical antipsychotics should undergo fasting blood glucose testing. . . .

Letter from Russell Katz, M.D., Dep't of Health & Human Servs., to Gregory T. Brophy, Ph.D., Eli Lilly & Co., Sept. 11, 2003, at 1-2. The label did not mention weight gain or diabetes in the "warning to patients" section.

Lilly added the FDA-required language to the Zyprexa label on September 16, 2003. *See* Zyprexa Package Insert (Sept. 16, 2003). At the FDA's request, on March 1, 2004, it sent a "Dear Doctor" letter to physicians in the United States informing them of the 2003 label change. *See In re Zyprexa Prods. Liab. Litig.*, 253 F.R.D. at 134-36.

2. Consensus Statement of American Diabetes Association and Other Learned Groups

In November 2003, the American Diabetes Association, American Psychiatric Association, American College of Clinical Endocrinologists, and the North American Association for the Study of Obesity convened a consensus development conference (the "ADA consensus conference") on the subject of the association between antipsychotic drugs and diabetes. An eight-member panel heard presentations from fourteen experts drawn from the fields of psychiatry, obesity, and diabetes, FDA representatives, and atypical antipsychotic drug manufacturers. The panel reviewed the relevant peer-reviewed English language scientific articles.

The ADA consensus conference concluded that Zyprexa and Clozaril posed an increased risk of diabetes as compared to other atypical antipsychotic drugs. The consensus statement produced by the conference declared that these relative risks as well as advantages of the drugs for individual patients in a heterogeneous population "should . . . influence drug choice." In part, its report concluded:

There is considerable evidence, particularly in patients with schizophrenia, that treatment with [atypical antipsychotics] can cause a rapid increase in body weight in the first few months of therapy that may not reach a plateau even after 1 year of treatment. There is, however, considerable variability in weight gain among the various [atypical antipsychotics] . . . .

***

Clozapine [Clozaril] and olanzapine [Zyprexa] . . . produce the greatest weight gain.

***

Despite limitations in study design, the data consistently show an increased risk for diabetes in patients treated with clozapine [Clozaril] or olanzapine [Zyprexa] compared with patients not receiving treatment with [first generation antipsychotics] or with other [atypical antipsychotics]. The risk in patients taking risperidone and quetiapine is less clear; some studies show an increased risk for diabetes, while others do not. The two most recently approved [atypical antipsychotics], aripiprazole and ziprasidone, have relatively limited epidemiological data, but available clinical trial experience with these drugs has not shown an increased risk for diabetes.

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[T]he risks of obesity, diabetes, and dyslipidemia have considerable clinical implications in this patient population and should . . . influence drug choice.

Even for those medications associated with an increased risk of metabolic side effects, the benefit to specific patients could outweigh the potential risks. For example, clozapine [Clozaril] has unique benefits for treatment-refractory patients and those at significant risk for suicidal behavior. Since treatment response in many psychiatric conditions is heterogeneous and unpredictable, physicians and patients can benefit from the availability of a broad array of different therapeutic agents.

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These three adverse conditions [obesity, diabetes, and dyslipidemia] are closely linked, and their prevalence appears to

> differ depending on the [atypical antipsychotic] used. Clozapine [Clozaril] and olanzapine [Zyprexa] are associated with the greatest weight gain and highest occurrence of diabetes and dyslipidemia. Risperidone and quetiapine appear to have intermediate effects. Aripiprazole and ziprasidone are associated with little or no significant weight gain, diabetes, or dyslipidemia, although they have not been used as extensively as other agents.
>
> The choice of [atypical antipsychotic] for a specific patient depends on many factors. The likelihood of developing severe metabolic disease should also be an important consideration.

American Diabetes Association, et al., Consensus Development Conference on Antipsychotic Drugs and Obesity and Diabetes, 27 Diabetes Care 596, 596-97 (Feb. 2004)

3. FDA March 2007 Letter

On March 27, 2007, the FDA raised new concerns about the adequacy of Zyprexa's warning label in a letter to Lilly:

> [W]e are concerned that the labeling is deficient with regard to information about weight gain, hyperglycemia, and hyperlipidemia that is associated with olanzapine [Zyprexa] use . . . .
>
> Our overall goal is to improve labeling with regard to these findings so that clinicians will be better informed on what the risks are for their patients. They cannot make reasonable treatment decisions until they have such information. We do not feel that current labeling for . . . Zyprexa provides sufficient information on these risks, and we fully intend to insure that . . . labels are enhanced with the best available information to characterize these risks.

In re Zyprexa Prods. Liab. Litig., 253 F.R.D. at 141 (quoting Letter from Thomas Laughren, FDA, to Robin Pitts Wojcieszek, Eli Lilly & Co., Mar. 27, 2007).

4. Findings on Medical Community's Knowledge of Zyprexa's Risks

A universally applicable date from which the statute of limitations is to be considered to run on an individual Zyprexa user's claim has not been determined. Numerous events represent moments at which a patient, health care provider, institution, or the medical community at large arguably discovered that the cause of an alleged injury may have been the administration of Zyprexa. The evidence in this mass litigation, including medical records and the depositions of numerous doctors, suggests that it was widely known and understood in the late 1990s among treating and prescribing physicians that weight gain might follow the administration of Zyprexa. The association between weight gain and heightened risk of diabetes was also broadly recognized by that time.

Formal events bringing this information to the medical profession include the September 2003 Zyprexa label change and contemporaneous press release, the 2003 consensus statement of the American Diabetes Association, and the March 2004 "Dear Doctor" letter distributed nationwide to physicians by Lilly.

In its June 2007 memorandum, order, and judgment on four motions for summary judgment in individual Zyprexa injury cases, this court found that, for purposes of these motions, the March 1, 2004 "Dear Doctor" letter would be considered the latest possible date on which members of the medical community knew or should have known about Zyprexa's obesity- and diabetes-related risks to patient health. *See, e.g., Souther v. Eli Lilly & Co. (In re Zyprexa Prods. Liab. Litig.)*, 489 F. Supp. 2d 230, 278 (E.D.N.Y. 2007). In *Souther*, applying the relevant "learned intermediary" doctrine, it was determined that Souther's claim was barred by the statute of limitations:

> Diabetes developed and Zyprexa was prescribed [to plaintiff Cusella] years before the September 2003 label change. *At least from the date of March 2004 Dear Doctor letter, the causal connection between Zyprexa and diabetes was known to Dr. Ganime, Cusella's treating physician.* Since Lilly's duty to warn ran to Dr. Gamine rather than Cusella, it became Dr. Ganime's duty from that point onwards to disclose to Cusella that Zyprexa might exacerbate his diabetes, and that it may have been the impetus behind Cusella's insulin-dependancy in the first place.
>
> Dr. Ganime's medical records and deposition testimony . . . show that Cusella was warned numerous times about the link between Zyprexa and diabetes. While the pre-label change warnings Dr. Ganime received from Lilly *may* not have been adequate to absolve Lilly of liability to Cusella, those warnings Cusella received from Dr. Ganime following the label change placed him on notice that use of Zyprexa might have worsened his diabetes and caused him to become insulin-dependent.
>
> *Measured either against the date Cusella developed diabetes—August 1999—or the latest possible date Dr. Gamine was aware of the potential causal connection between Zyprexa and diabetes—March 2004*—Pennsylvania's two year statute of limitations had run on Cusella's claim before he filed this suit in April of 2006.

Id. (emphases added; citations to record omitted).

The March 1, 2004 date represents the "latest possible date" prescribing physicians and, in effect, their patients are deemed aware of the potential causal connection between Zyprexa and diabetes and from which the statute of limitations may run as to any individual plaintiff. Nevertheless, a fact-specific analysis is necessary for each case to determine when the plaintiff – whether independently or by operation of the learned intermediary doctrine – knew the potential causal connection between Zyprexa and adverse health effects. The facts in many individual cases indicate a much earlier date of discovery for purposes of the statute of limitations. *See, e.g.*, Appendices A-D of *Souther v. Eli Lilly & Co. (In re Zyprexa Prods. Liab. Litig.)*, Nos. 04-MD-1596, 06-CV-1729, Docket Entries Nos. 88-1 to 88-4 (E.D.N.Y. June 11, 2007) (including

relevant depositions demonstrating doctors' awareness of Zyprexa's association with patient weight gain).

C. Medical History and Treating Physicians' Decision to Prescribe Zyprexa

William Asbury is a 61 year-old Caucasian male. He resides in St. George, Kansas. Plaintiff's Fact Sheet at 2 (Brenner Decl., Ex. 4). He is a disabled Vietnam veteran, Asbury Dep. at 27:7-28:6, 31:21-32:5 (Brenner Decl., Ex. 2), and has suffered from obesity and drug and alcohol abuse. ASBURYW_SSA_0110 (Brenner Decl., Ex. 3); Asbury Dep. 25:7-26-10.

Since 1975, Asbury has suffered from schizophrenia and schizoaffective disorder, and has experienced auditory and visual hallucinations. Asbury Dep. 60:7-19, 64:22-65:6; ASBURYW_COVMC_0362 (Mar. 14, 1995 Discharge Summary, Brenner Decl., Ex. 5). His illness has prevented him from having a close relationship with his family. Asbury Dep. 57:14-61:6.

Asbury was hospitalized at least twice a month from 1975 until 1980 at the Brecksville Veterans Hospital for schizophrenia, depression, and suicide attempts. *Id.* 44:13-45:8. In 1980, he was hospitalized at the Colmery-O'Neil Veterans Hospital for ten months. *Id.* 44:13-25. Later in 1980, he was hospitalized in Anchorage, Alaska for schizophrenia, depression, and mania. *Id.* 48:20-25.

Asbury attempted suicide or made suicidal gestures several times. *Id.* 65:13-25. He was prescribed first generation antipsychotics, but experienced side effects from these medications including dry mouth, sleepiness, and "zombie-like behavior." *Id.* 51:4-52:15

Zyprexa was prescribed from November 24, 1997 to 2007. ASBURYW_COVMC_0292 (Nov. 24, 1997 Progress Note, Brenner Decl, Ex. 5); Asbury Dep. 53:13-14. Dr. John Pope, a

psychiatrist with the Colmery O'Neil Veterans Affairs Hospital, was the only physician who prescribed Zyprexa to Asbury. Plaintiff's Fact Sheet at 5. Dr. Pope changed him from Haldol to Zyprexa due to the emergence of preliminary symptoms of tardive dyskinesia. ASBURYW_COVMC_0439-40 (Jan. 12, 1998 Health Summary, Brenner Decl., Ex. 5).

Zyprexa was effective in treating Asbury's mental illness. Asbury Dep. 52:23-25. It reduced his auditory hallucinations "from all day, every day . . . down to two or three times a month." *Id.* 53:3-5. In 2003 and 2004 medical records show that Asbury was not experiencing suicidal thoughts and his mood was stable. ASBURYW_COVMC_0093 (Apr. 7, 2003 Progress Note, Brenner Decl., Ex. 5); ASBURYW_COVMC_0082 (Jan. 7, 2004 Progress Note, Brenner Decl., Ex. 5). As of October 2005, Asbury had not been hospitalized since he began taking Zyprexa. ASBURYW_COVMC_0032 (Oct. 24, 2005 Progress Note, Brenner Decl., Ex. 5).

In May 2001, Dr. Pope noted that because Asbury was able to lose weight on Zyprexa he did not want to take him off of it. ASBURYW_COVMC_0141 (May 30, 2001 Progress Note, Brenner Decl., Ex. 5).

Asbury was diagnosed with diabetes by January 12, 1998, approximately six weeks after he started taking Zyprexa. ASBURYW_COVMC_0439-40. His treating physician, Dr. Jayendra Patel, testified that he was aware in May 2000 that Zyprexa could be associated with symptoms of diabetes and that he told Asbury at that time that Zyprexa may be associated with his diabetic symptoms. Patel Dep. 43:4-45:19 (Brenner Decl., Ex. 6).

III. Law

A. Summary Judgment Standard

Summary judgment is appropriate only if "there is no genuine issue as to any material fact and if the moving party is entitled to a judgment as a matter of law." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 250 (1986); *see also Mitchell v. Washingtonville Central School District*, 190 F.3d 1, 5 (2d Cir. 1999). Summary judgment is warranted when after construing the evidence in the light most favorable to the non-moving party and drawing all reasonable inferences in its favor, there is no genuine issue as to any material fact. Fed. R. Civ. P. 56(c); *see Anderson*, 477 U.S. at 247-50, 255; *Sledge v. Kooi*, 556 F.3d 137, 140 (2d Cir. 2009).

The burden rests on the moving party to demonstrate the absence of a genuine issue of material fact. *Goenaga v. March of Dimes Birth Defects Found.*, 51 F.3d 14, 18 (2d Cir. 1995); *see also Celotex Corp. v. Catrett*, 477 U.S. 317, 322-23 (1986). If the moving party appears to meet this burden, the opposing party must produce evidence that raises a material question of fact to defeat the motion. *See* Fed. R. Civ. P. 56(e). This evidence may not consist of "mere conclusory allegations, speculation or conjecture[.]" *Cifarelli v. Village of Babylon*, 93 F.3d 47, 51 (2d Cir. 1996); *see also Delaware & Hudson Ry. v. Consolidated Rail Corp.*, 902 F.2d 174, 178 (2d Cir. 1990) ("Conclusory allegations will not suffice to create a genuine issue.").

B. Choice of Law

A multidistrict litigation transferee court applies the choice of law and statute of limitations rules of the state in which the action was filed. *Menowitz v. Brown*, 991 F.2d 36, 40 (2d Cir. 1993) (citing *Van Dusen v. Barrack*, 376 U.S. 612 (1964)). Because the instant action was originally commenced in Kansas, Kansas choice of law principles apply.

Plaintiff resided in Kansas when he took Zyprexa and when he was diagnosed with his injury. Kansas choice of law analysis requires that Kansas substantive law apply. *Brown* v. *Kleen Kut Mfg. Co.*, 714 P.2d 942, 944 (Kan. 1986) ("[T]he law of the state where the tort occurred is applied to the substantive rights of the parties.").

C. Kansas Statute of Limitations

Kansas applies a two-year limitation to actions for personal injury actions. K.S.A. § 60-513(a)(4). A cause of action for personal injury accrues when "the act giving rise to the cause of action first causes substantial injury, or, if the fact of injury is not reasonably ascertainable until some time after the initial act, then the period of limitation shall not commence until the fact of injury becomes reasonably ascertainable to the injured party." K.S.A. § 60-513(b). The Kansas Supreme Court has interpreted this discovery rule provision to mean that the statute of limitations starts to run "at the time a negligent act causes injury if both the act and the resulting injury are reasonably ascertainable by the injured person." *Moon v. City of Lawrence,* 982 P.2d 388, 394 (Kan. 1999).

IV. Application of Law to Facts

Asbury was diagnosed with diabetes no later than January 12, 1998. ASBURYW_COVMC_0439-40. Dr. Patel testified that he was aware in May 2000 that Zyprexa could be associated with symptoms of diabetes and that he told Asbury that Zyprexa may be associated with his diabetic symptoms. Patel Dep. 43:4-45:19

Asbury called his attorney in 2003 after he saw a television advertisement saying that if he had taken Zyprexa and was diagnosed with diabetes that he could file for a lawsuit. Asbury Dep. 33:7-11.

The injury and its claimed relationship to Zyprexa became "reasonably ascertainable" no later than the end of 2003. Asbury filed his Complaint on January 31, 2006, after the statute of limitations had run.

V. Conclusion

Summary judgment against the plaintiff is granted on the basis of the statute of limitations.

SO ORDERED.

Jack B. Weinstein
Senior United States District Judge

Date: March 26, 2010
Brooklyn, New York